4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-P-2060]

Determination That Levitra (Vardenafil Hydrochloride) Oral Tablets, 5 Milligrams, 10 Milligrams, and 20 Milligrams, Were Not Withdrawn from Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that Levitra (vardenafil hydrochloride) oral tablets, 5 milligrams (mg), 10 mg, and 20 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to these products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Daniel Ritterbeck, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6219, Silver Spring, MD 20993-0002, 301-796-4673, Daniel.Ritterbeck@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Levitra (vardenafil hydrochloride) oral tablets, 5 mg, 10 mg and 20 mg, are the subject of NDA 021400, held by Bayer HealthCare Pharmaceuticals, Inc., and initially approved on August 19, 2003. Levitra is a phosphodiesterase 5 inhibitor indicated for the treatment of erectile dysfunction.

In letters dated September 26, 2019, September 24, 2020, and September 20, 2021, Bayer HealthCare Pharmaceuticals, Inc. notified FDA that Levitra (vardenafil hydrochloride) oral tablets, 5 mg, 10mg and 20mg, respectively, were being discontinued, and FDA moved the drug products to the "Discontinued Drug Product List" section of the Orange Book.

Respira Therapeutics, Inc. submitted a citizen petition dated August 29, 2022 (Docket No. FDA-2022-P-2060), under 21 CFR 10.30, requesting that the Agency determine whether Levitra (vardenafil hydrochloride) oral tablets, 20mg, were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 5 mg and 10 mg strengths, those strengths have also been discontinued. On our own initiative, we have also determined whether those strengths were withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that Levitra (vardenafil hydrochloride) oral tablets, 5 mg, 10 mg, and 20 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of Levitra (vardenafil hydrochloride) oral tablets, 5 mg, 10 mg, and 20 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list Levitra (vardenafil hydrochloride) oral tablets, 5 mg, 10 mg, and 20 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to these drug products. Additional ANDAs for these drug products may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-09365 Filed: 5/2/2023 8:45 am; Publication Date: 5/3/2023]